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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/508,661	05/26/00	SACHETTO J	

EXAMINER	
DEWITTY, R	
ART UNIT	PAPER NUMBER
1616	8

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/508,661	SACHETTO ET AL.	
	Examiner	Art Unit	
	Robert M DeWitty	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 22-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 22-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other:

DETAILED ACTION

Claims 1-15 and 22-28 are pending in the instant application.

Claims 16-21 are withdrawn. Cancelled

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1, 9, 11, 13, 14, and 27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, regarding claim 1, the specification does not teach a rectally administerable delayed release oral, rather the specification only teaches a post-gastrically available delayed release oral or rectally administerable pharmaceutical composition (page 5, line 21-23). Regarding claim 9, the specification does not teach xanthan gum in an enema from about 0.4% to about 2%, but rather teaches xanthan gum in an enema from 0.2% to 2% (page 8, line 7). Regarding claim 11, the specification does not teach HPMC for a liquid enema from about 1 to about 20%, but rather teaches HPMC from 0.2% to 20% (page 9, lines 11-12). Regarding claim 13, the specification does not teach xanthan gum in an enema or foam from about 400 to about 2000 mg, rather it teaches xanthan gum from 200 to 2000 mg (page. 7, line 38). Regarding claim 14, the specification does not teach

HPMC in an amount of about 1 to about 20 g, rather it teaches HPMC from 0.2 to 20 g (page 9, lines 7-8). Regarding claim 27, the specification does not teach xanthan gum in an amount from about 0.4 to about 2%, rather it teaches xanthan gum from 0.2 to 2%.

The above claims were thus not examined in their amended form.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 1 contains an improper Markush grouping. Correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 9, and 27-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Day.

Day (WO 94/04136) teaches a method of treating or preventing irritable bowel

sndrome consisting of orally administering an amount of an anion-binding polymer and a hydrophilic polymer. The anion-binding polymer can be xanthan gum (page 7, line 26). The pharmaceutical composition can have a total amount of polymer per dose of about 1g to 24 g (page 9, line 6). The weight ratio between the anion-binding polymer to the hydrophilic polymer can be about 2:1 to about 1:2 (Id. at line 9).

Thus, the above claims are anticipated.

4. Claims 1, 3-5, 7, 8, 11, 12, 14-15, 22-26 rejected under 35 U.S.C. 102(b)as being anticipated by Astra Aktiebolag.

Astra Aktiebolag (WO 98/01112) teaches hydrogel formulation for the treatment of distal inflammatory bowel diseases. The hydrogel is comprised of one or more gelling agents, suitable gelling agents including hydroxypropylmethylcellulose (page 3, line 1). In examples given, hydroxypropylmethylcellulose is used in an amount of 0.2 g to 2.45 g (*see* Examples 1-3).

Thus, the claims are anticipated.

5. Claims 1, 10 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Slagel.

Slagel (WO 96/03115) teaches that pharmaceutical compositions exhibiting a delayed foaming action are particularly suitable for rectal or vaginal administration because the likelihood of inducing a defecation or rejection reflex on administration of the composition is much lower, and a better spreading effect is obtained, leading to

increased bioavailability of the active substance (page 1, line 35-page 2, line 5). At Example 1, pages 12 and 13, Slagel teaches 2 g of xanthan gum used in a foamable composition, results showing that all components are necessary for use of the invention.

Thus, the above claims are anticipated.

6. Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Sandborn.

Sandborn (WO 96/30021) teaches a method of treating inflammatory bowel Disease comprising administering an amount of AZA by means of an enteric-coated unit dosage form. It is further taught that hydroxypropylmethylcellulose phthalate is a polymer suitable for use in the composition.

Thus, the claims are anticipated.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone number for the organization where this application or proceeding is assigned is 703-308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD
April 20, 2001

JOSE' G. FEES
SUPERVISORY PATENT EXAMINER
1616